



ENDIUS.013A

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Alan E. Shluzas et al.
Appl. No. : 10/678,744
Filed : October 2, 2003
For : MINIMALLY INVASIVE
ACCESS DEVICE AND
METHOD
Examiner : James L. Swiger III
Group Art Unit : 3733

DECLARATION OF GENE P. DIPOTO PURSUANT TO 37 C.F.R. § 1.131

Mail Stop Amendment

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Dear Sir:

This declaration is to establish an invention date of embodiments claimed in the above-captioned patent application before October 30, 2001, the filing date of U.S. Publication No. 2003/0083688 A1 to Simonson. I, Gene P. DiPoto, do declare as follows:

1. I am a named inventor of the above-captioned patent application and am familiar with the prosecution of the application, including the Amendment accompanying this Declaration.

2. I am advised by my attorneys that Claims 1-38 of the present application are rejected in the August 1, 2006 Office Action as being unpatentable over Davison et al. (U.S. Patent No. 6,187,000 B1) in view of Simonson (U.S. Publication No. 2003/0083688 A1).

3. I believe that the facts set forth below show that I conceived and reduced to practice embodiments of the claimed invention, as amended by the Amendment referred to above, prior to the October 30, 2001 filing date of the Simonson reference.

4. Exhibit A includes sketches I made on a sheet of paper prior to the October 30, 2001 filing date of the Simonson reference of a retractor with an oval proximal end. The figure of the oval retractor included dimensions for the oval proximal end. In addition, the oval retractor was drawn with a distal end in an expanded configuration. This sheet of paper was

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stapled to additional sheets of paper, the first of which bore a date prior to the October 30, 2001 filing date of the Simonson reference.

5. Exhibit B includes a fax enclosing sketches of two non-expanding oval cannulas that I sent to Dr. Gil Aust. The date of the fax is prior to the October 30, 2001 filing date of Simonson, with the date having been redacted. The sketches included the dimensions of the two oval cannulas. In the comments section on the fax cover page, I stated that an expandable skirt mechanism may need to be riveted and could comprise two pieces.

6. Exhibit C includes an email I sent Dr. Gil Aust informing him that I would be sending him a prototype of the oval cannula by overnight mail. This email also refers to prototypes that I had made of an oval cannula having a paper skirt. In the email I informed Dr. Aust that the skirt may need to have two rivets with one rivet capable of sliding. The prototypes that I had made included a straight oval cannula formed of metal and a paper skirt attached to the oval cannula that was expandable to make a distal portion of the skirt larger than a proximal portion of the skirt. These prototypes included a version having a skirt made of a single piece of material and a skirt made of two pieces of material. The date of the email is prior to the October 30, 2001 filing date of Simonson, with the date having been redacted.

7. Exhibit D includes a note I sent Dr. Gil Aust with pictures of a non-expanding oval cannula prototype and a sketch of an expandable one piece skirt design. This date of this note is prior to the October 30, 2001 filing date of Simonson, with the date having been redacted.

8. At the time I made the prototypes of the oval cannulas having an expandable skirt as described above, I contemplated that the skirt would be made out of metal, much like the skirts that had previously been made for expandable retractors having round proximal ends. See, for example, the retractors described in U.S. Patent No. 6,187,000 to Davison. I believe that a person of ordinary skill in the art at the time would have recognized that the skirt of my prototype could be made out of metal in order for it to be more suitable for insertion into a patient.

9. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United

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States Code and that such willful, false statements may jeopardize the validity of the application or any patent issued thereon.

Dated: 1- Dec -2006

By: Gene P. DiPoto
Gene P. DiPoto

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